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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,032	01/21/2005	Hiroaki Kambayashi	009682-142	1529

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
04/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/522,032	KAMBAYASHI ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *13-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 12/13/07.

The amendment filed 12/13/07 affects the application, 10/522,032 as follows:

1. Claims 1-8 have been amended. New Claims 9-24 have been added.

2. The responsive to applicants' arguments is contained herein below.

Claims 1-24 are pending in application

Newly submitted and amended claims 13-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 13 recites, "A method for treating wrinkles, acne, coarse textured skin, and/or rough skin, and/or for whitening the skin, wherein said method comprises topically applying to the skin a composition comprising at least one acyl glucosamine derivative represented by the following Formula (I): …." Claim 21 is also drawn to a method for treating wrinkles, acne, coarse textured skin, and/or rough skin, and/or for whitening the skin. However, claims drawn to a method was not originally examined, is a different or distinct invention which pertains to said method of treating wrinkles acne, coarse textured skin, and/or rough skin, and/or for whitening the skin and which would involve a different and burdensome search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 13-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Note that a reference to the composition herein would not necessarily be a reference to the method of using herein under 35 USC 103. The composition and method herein have separate consideration as to patentability.

Claim Rejections - 35 USC § 102

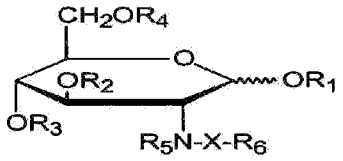
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Della Valle et al. (WO 96/18600).

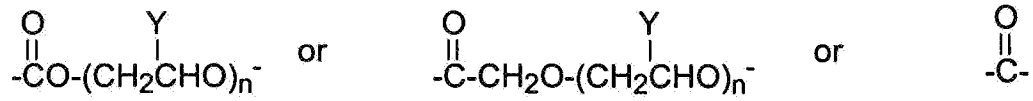
In claim 1, applicant claims an external preparation composition comprising (a) at least one acyl glucosamine derivative represented by the following Formula (I):



(I)

wherein R_1, R_2, R_3 and R_4 each represent a hydrogen atom, a saturated or unsaturated, linear or branched fatty acid residue having 2 to 36 carbon atoms or a linear or branched alkyl group having 1 to 4 carbon atoms which may have a hydroxyl group, wherein R1, R2, R3 and R4 may be the same or different; R_5 represents a hydrogen atom or a linear or branched alkyl group having 1 to 4 carbon atoms which may have a hydroxyl group; X is any one of the groups represented by the following Formulas (A) to (C):

(A) (B) (C)



wherein Y in (A) and (B) represents a hydrogen atom or an alkyl group having 1 to 5 carbon atoms in which an ether group may be interposed into a bond; and n represents an integer of 0 to 10; and R_6 represents a linear or branched alkyl group or alkenyl group having 11 to 36 carbon atoms which may have a substituent; and at least one percutaneous absorption accelerator selected from the group consisting of isopropyl palmitate, isopropyl myristate, diisopropyl adipate, dioctyl succinate octyldodecyl lactate, oleic acid, ethyl oleate, decyl oleate, oleyl oleate, octyldodecyl oleate, propylene glycol oleate, urea and its derivatives, glyolic acid and its salts, lactic acid and its salts, salicyclic acid, ethanol, isopropanol, propylene glycol, dipropylene glycol, 1,3-butylene glycol, polyethylene glycol, cyclodextrin, polyethylene glycol/polydimethylsiloxane copolymers and creatinine. Della Valle et al. disclose applicant's composition of an acyl glucosamine derivative (N-lauroyl-D- glucosamine) represented by the following Formula (I): wherein R_1, R_2, R_3 and R_4 represent a hydrogen atom; R_5 represents a hydrogen atom; X is represented by the following Formula (C):  and R_6 represents a linear alkyl group having 11 carbon atoms and ethanol (see page 23, example 14 to page 24, line 20). It should be noted that Della Valle et al.'s compound is in or together with ethanol (see page 23, example 14 to page 24, line 20). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for external use or an external preparation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

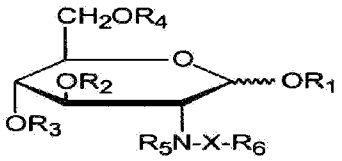
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al. (WO 96/18600).

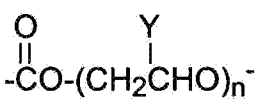
In claim 1, applicant claims an external preparation composition comprising (a) at least one acyl glucosamine derivative represented by the following Formula (I):



(I)

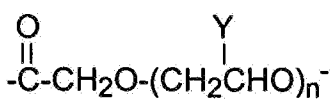
wherein R_1, R_2, R_3 and R_4 each represent a hydrogen atom, a saturated or unsaturated, linear or branched fatty acid residue having 2 to 36 carbon atoms or a linear or branched alkyl group having 1 to 4 carbon atoms which may have a hydroxyl group, wherein R1, R2, R3 and R4 may be the same or different; R_5 represents a hydrogen atom or a linear or branched alkyl group having 1 to 4 carbon atoms which may have a hydroxyl group; X is any one of the groups represented by the following Formulas (A) to (C):

(A)



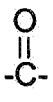
or

(B)



or

(C)



wherein Y in (A) and (B) represents a hydrogen atom or an alkyl group having 1 to 5 carbon atoms in which an ether group may be interposed into a bond; and n represents an integer of 0 to 10; and R_6 represents a linear or branched alkyl group or alkenyl group having 11 to 36 carbon atoms which may have a substituent; and at least one percutaneous absorption accelerator selected from the group consisting of isopropyl palmitate, isopropyl myristate, diisopropyl adipate, dioctyl succinate octyldodecyl lactate, oleic acid, ethyl oleate, decyl oleate, oleyl oleate, octyldodecyl oleate, propylene glycol oleate, urea and its derivatives, glyolic acid and its salts, lactic acid and its salts, salicyclic acid, ethanol, isopropanol, propylene glycol, dipropylene glycol, 1,3-butylene glycol, polyethylene glycol, cyclodextrin, polyethylene glycol/polydimethylsiloxane copolymers and creatinine. Claims 2-12 are drawn to said external preparation or composition further comprising chemically active substance having skin care effect, said composition further comprising a silicone oil and a silicone derivative and comprising specific acyl glucoseamine derivatives.

Della Valle et al. disclose a composition of an acyl glucosamine derivative (N-lauroyl-D-glucosamine) represented by the following Formula (I): wherein R_1, R_2, R_3 and R_4 represent a hydrogen atom; R_5 represents a hydrogen atom; X is represented by the following Formula (C):  and R_6 represents a linear alkyl group having 11 carbon atoms and ethanol (see page 23, example 14 to page 24, line 20). It should be noted that Della Valle et al.'s compound is in or together with ethanol (see page 23, example 14 to page 24, line 20). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for external use or an external

preparation, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, Della Valle et al. disclose that their compounds (which include N-lauroyl-D- glucosamine) can be treat several disease like those connected to an anomalous modulation of CB2 peripheral receptor etc, and that different formulations which includes solution, suspension, powder, tablets, pills, creams ointments and gels can be prepared depending on the type of administration required (see page 49, line 13 to page 52, line 21). In addition, Della Valle et al. disclose that their compounds can be administered by oral or parental or topical or transdermal ways (see 50, line 27 to 51, line 2).

The difference between applicant's composition and the composition of Della Valle et al. is that Della Valle et al.'s composition do not contain skin care active substance and silicon oil or silicone derivatives. However, one would be motivated to combine Della Valle et al.'s compound (N-lauroyl-D- glucosamine) with other emulsifying agents or emulsifiers such as silicone oil or silicon oil derivatives and skin care active substance in order to use them in pharmacy to prepare emulsions such as creams and lotions for topical application to the skin, since Della Valle disclose that their compounds can be prepared in formulations such as creams and lotions.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Della Valle et al., to prepare a composition comprising a combination of Della Valle et al.'s emulsifying agent (N-lauroyl-D- glucosamine) with other emulsifying agents or emulsifiers such as silicone oil or silicon oil derivatives and skin care active substance, since the Della Valle disclose that their compounds can be prepared in formulations such as creams and lotions.

One having ordinary skill in the art would have been motivated in view of Della Valle et al., to prepare a composition comprising a combination of Della Valle et al.'s compound or emulsifying agent (N-lauroyl-D-glucosamine) with other emulsifying agents or emulsifiers such as silicone oil or silicon oil derivatives and skin care active substance in order to use them in pharmacy to prepare emulsions such as creams and lotions for topical application to the skin, based on need, like the type of cream or lotion desired and the type and/or condition of skin to be treated. It should be noted that the preparation or use of acyl glucosamine derivatives such as N-retinoyl-D-glucosamine and N-isostearoyl-D-glucosamine is also encompassed by this rejection since Della Valle et al. also disclose that the hydrocarbon radical (which represents R_6 in applicant's compound of Formula (I) can contain from 9 to 23 carbons atoms) (see page 6, line 6 to 16).

Response to Arguments

Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37